Government of the District of Columbia
Office of the Chief Financial Officer

Natwar M. Gandhi
Chief Financial Officer

MEMORANDUM

TO: **The Honorable Vincent C. Gray**
Chairman, Council of the District of Columbia

FROM: **Natwar M. Gandhi**
Chief Financial Officer

DATE: **October 2, 2009**

SUBJECT: **Fiscal Impact Statement: "Unused Pharmaceutical Safe Disposal Act of 2009"**

REFERENCE: **Bill 18-239, Draft Committee Print**

Conclusion

Revenues are sufficient in the FY 2010 through FY 2013 budget and financial plan to implement the provisions of the proposed legislation; special purpose revenue budget authority would need to be provided through a reprogramming. The estimated cost for implementing the Unused Pharmaceutical Safe Disposal Program would be approximately $170,000 in FY 2010 and $799,000 over the FY 2010 through FY 2013 period. The Department of Health (DOH) has confirmed that DOH and more specifically the Board of Pharmacy could cover these costs with their expected revenues and fund balance.

Background

The proposed legislation would require the Mayor to establish and implement[1] the Unused Pharmaceutical Safe Disposal Program ("Program"), a mail-in pharmaceutical return program that would: a) provide District residents with prepaid mailing envelopes in which to return their unused pharmaceuticals, including controlled substances; b) distribute these envelopes to all retail pharmacies, as well as other various locations; and c) arrange for the safe disposal of the collected pharmaceuticals. In addition, the proposed legislation would require that the Board of Pharmacy design a public education campaign concerning the disposal of pharmaceuticals and that retail pharmacies implement the campaign. Lastly, it would prohibit health care facilities from disposing

[1] By July 1, 2010.

of any pharmaceutical products via the public sewer system and would impose a civil fine for noncompliance.

The Program would have to comply with the federal Controlled Substances Act[2], which specifies that the lawful owner of a prescription medication (both controlled and noncontrolled)[3] is allowed to mail his medication, but only to an entity registered with the Drug Enforcement Administration (DEA) or one that is exempt from registration, such as a law enforcement agency like the Metropolitan Police Department (MPD). Similarly, the Program would have to follow DEA's regulations concerning the destruction of controlled substances,[4] which require that at least two people witness the incineration (generally referred to as a "witnessed burn") and that the destruction be carried out by a entity exempt from statutorily registration or one that has registered with the DEA.[5]

Thus, a decision would have to be made as to who would be responsible for accepting and destroying the drugs. There are two basic options. First, all envelopes would be sent to the DEA or a DEA exempt agency. The envelopes would then be opened and the controlled drugs would be separated from the noncontrolled drugs.[6] The controlled drugs would be destroyed locally, with two witnesses present, while the noncontrolled drugs would be shipped out to a hazardous facility for destruction.[7]

The second option would be to use a licensed reverse distributor.[8] However, in addition to complying with DEA's record-keeping and security regulations, the reverse distributor would also have to get a waiver from DEA to accept drugs from individuals. The entity would destroy all the drugs together, thus requiring two witnesses be present at *all* incinerations.

For purposes of this analysis, we assume the former since it would not require any special waiver and it most closely mirrors what is currently done in Maine, [9] the only state that has implemented a

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[2] Enacted into law as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.

[3] Controlled medications are regulated by the U.S. Drug Enforcement Administration and are drugs, or other substances, included in Schedule I, II, III, IV, or V of the Controlled Substances Act in 21 U.S.C. § 801 and the implementing regulations in 21 CFR § 1300.They include heroin, marijuana, morphine, OxyContin®, Vicodin®, Xanax® and cough medicines with codeine.

[4] Noncontrolled substances can be destroyed by using a hazardous waste company.

[5] DEA is currently considering easing the rules and regulations governing the disposal of controlled substances. http://edocket.access.gpo.gov/2009/pdf/E9-1056.pdf

[6] This may require an exemption from the DEA.

[7] All drugs could also be destroyed locally by the DEA or DEA exempt agency, but this is more costly.

[8] A reverse distributor (RD) is a business that manages certain pharmaceuticals typically shipped from a licensed pharmacy. The term and category of "reverse distributor" was codified in May 2005 with the amendment of Title 21 Code of Federal Regulations (CFR) 1300.01 (b)(41). The amendments established the regulatory standards under which reverse distributors may handle unwanted, unusable, or outdated controlled substances acquired from another DEA registrant. RDs must register, provide security, and maintain accurate records for all controlled substances in their possession. In August 2008, there were a total of 45 RDs nationwide. A reverse distributor made a presentation to Council staff and it specified that they were not able to accept controlled substances.

[9] In Maine, all drugs are sent to the Maine DEA. They are then sorted and the controlled are destroyed locally and

pharmaceutical mailback program.[10] Other states and jurisdictions have implemented programs to return pharmaceuticals, but their programs have involved secure receptacles at pharmacies, police departments, hazardous materials facilities and/or health clinics, as well as single-day collection events.[11]

Financial Plan Impact

Revenues are sufficient in the FY 2010 through FY 2013 budget and financial plan to implement the provisions of the proposed legislation; special purpose revenue budget authority would need to be provided through a reprogramming. The estimated cost for implementing the Unused Pharmaceutical Safe Disposal Program would be approximately $170,000 in FY 2010 and $799,000 over the FY 2010 through FY 2013 period. DOH has confirmed that the Board of Pharmacy could cover these costs with their expected revenues and fund balance,[12] which fund balance is estimated to total approximately $1.3 million at the beginning of FY 2010.

The pharmaceutical industry estimates that about 3 percent of prescribed drugs are unused and disposed of via the trash or sewer.[13] Of those unused drugs, 66 percent are estimated to be for individual use, while the remaining 34 percent are for long-term care facilities. Using this information and data from the Kaiser Family Foundation on the number of prescriptions filled in D.C. at retail pharmacies and via mail-order,[14] it is estimated that there would be approximately 114,000 unused prescriptions for *individual* use in the District in 2010. Individual use is the focus of this analysis, as this is the target of the Program; health care facilities would be responsible for disposing of their unused pharmaceuticals in an appropriate manner.

In order to determine the specific costs for implementing and running the Program, the analysis relied heavily on the line item budget for the Safe Medicine Disposal for Maine.[15] Differences

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the noncontrolled are sent off to a hazardous waste facility for destruction. Ten percent of all returned drugs have been controlled substances.

[10] See http://www.safemeddisposal.com for more information on Maine's program.

[11] Funding for these programs has been diverse: from EPA grants to local dollars to in-kind donations. In British Columbia, which has one of the oldest and most extensive drop-off return programs, the pharmaceuticals industry funds the entire program.

[12] The Board of Pharmacy is supported by the Pharmacy Protection Fund, a special purpose (O-Type) revenue fund.

[13] Buzby, Mary E. 2007. Pharmaceuticals in the Environment: PhRMA PIE Perspective [Presentation], May 22 2007 [cited May 30 2007]. Available from http://www.dtsc.ca.gov/AssessingRisk/PPCP/upload/04_Buzby.pdf.

[14] According to industry statistics reported by The National Association of Chain Drug Stores and published by The Kaiser Family Foundation (http://statehealthfacts.org.), there were 5,094,063 prescriptions filled at pharmacies in D.C. in 2008. Retail prescriptions filled by mail order totaled another 6.7 percent. A growth rate of 3 percent per year was used to project prescriptions for 2010 through 2013.

[15] The Office of Revenue Analysis (ORA) was given the line-by-line budget for FY 2010 through FY 2012 for the Safe Medicine Disposal for Maine program by the University of Maine Center on Aging, which oversees the administration and coordination of the program. ORA also used other research on pharmaceutical return programs, including "The Oregon Pharmaceutical Take Back Stakeholder Group Final Report," July 2007.

between these two programs were taken into consideration in the final analysis, as was input from DOH and the Board of Pharmacy.

Estimated Cost for Unused Pharmaceutical Safe Disposal Program					
	FY 2010	**FY 2011**	**FY 2012**	**FY 2013**	**Four-Year Total**
Envelopes and Assembly[1]	$17,126	$29,200	$23,608	$24,316	$94,251
Marketing and User Support[2]	$5,000	$5,000	$2,500	$2,500	$15,000
Postage and Fees[3]	$18,765	$37,675	$38,777	$39,913	$135,130
Disposal[4]	$34,272	$69,400	$70,282	$71,190	$245,144
Program Staff[5]	$94,500	$81,000	$67,500	$66,400	$309,400
Total Cost	**$169,663**	**$222,275**	**$202,667**	**$204,320**	**$798,924**

Assumptions:

- On average, people would return 2 prescriptions per envelope.
- 0.5 pounds of unused pharmaceuticals would be returned per envelope
- 25 percent of all available envelopes would be returned
- At the end of each year, there would be an inventory of remaining envelopes.
- In FY 2010 only half of the number of envelopes needed to cover all unused individual pharmaceuticals would be distributed so that the Program could be adjusted accordingly in the out years.

Table Notes:

[1] Cost of buying the envelopes, printing instructions and inserting them in the envelopes

[2] Retail pharmacies would be required to implement a public education campaign; however a minimal amount of funds is still included for any government marketing costs.

[3] Postage is only paid on returned envelopes.

[4] Cost of DEA/DEA-exempt agency time to witness and destroy noncontrolled substances, and sort noncontrolled substances from controlled; and for noncontrolled to be shipped out to a hazardous facility and destroyed.

[5] Cost for a part-time Program Analyst and a Staff Assistant. Their hours would diminish over time due to declining program and administrative needs after the first two years.